

Amendments to the Claims:

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1-62. Cancelled

63-76. (Withdrawn)

77. (Currently Amended) A kit for use in screening a sample of body fluid for autoantibodies to ~~(i) a thyroid stimulating hormone (TSH) the TSH receptor, or (ii) at least a TSH receptor fragment,~~ which kit comprises:

(a) a source of ~~(i) a TSH receptor or (ii) a TSH receptor fragment,~~ said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ each having comprising at least first and second distinct epitope regions, wherein autoantibodies to said ~~(i) the TSH receptor or (ii) TSH receptor fragment~~ bind to said first epitope region but not said second epitope region;

(b) at least one antibody, or fragment thereof, that binds to said second epitope region of said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ of (a);

(c) means for contacting said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ of (a) with at least said sample of body fluid being screened and said antibody of (b), whereby said contacting means allow:

autoantibodies when present in said sample of body fluid being screened to bind to said first epitope region of said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ of (a); and

said antibody of (b) to bind to said second epitope region of said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ of (a); and

(d) means for monitoring binding of said autoantibodies and said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ of (a), so as to provide an indication of the presence of TSH receptor autoantibodies to said ~~(i) TSH receptor or (ii) TSH receptor fragment~~ in said sample of body fluid being screened.

78. (Currently Amended) A kit according to claim 77, wherein said antibody of (b) comprises a monoclonal antibody, or a recombinant antibody, or fragment thereof that binds to said second epitope region of said (i) TSH receptor ~~or (ii) TSH receptor fragment~~.

79. (Previously presented) A kit according to claim 77, wherein said antibody of (b) comprises a monoclonal antibody or fragment thereof obtainable by the Examples.

80. (Previously presented) A kit according to claim 77, wherein said antibody of (b) is immobilized to a solid phase.

81. (Previously presented) A kit according to claim 77, wherein said antibody of (b) is labeled.

82. (Currently Amended) A kit according to claim 77, wherein said contacting means enables contact of said antibody of (b) with said (i) TSH receptor ~~or (ii) TSH receptor fragment~~ prior to contact of said (i) TSH receptor ~~or (ii) TSH receptor fragment~~ with said sample of body fluid being screened.

83. (Currently Amended) A kit according to claim 77, wherein said contacting means enables contact of said antibody of (b) with said (i) TSH receptor ~~or (ii) TSH receptor fragment~~ concurrent with or after contact of said (i) TSH receptor ~~or (ii) TSH receptor fragment~~ with said sample of body fluid being screened.

84. (Currently Amended) A kit according to claim 77, which further comprises a competitor that binds with said first epitope of said (i) TSH receptor ~~or (ii) TSH receptor fragment~~ and whereby said contacting means enables contact of said competitor with said (i) TSH receptor ~~or (ii) TSH receptor fragment~~.

85. (Previously presented) A kit according to claim 84, wherein said competitor is selected from the group consisting of TSH, a monoclonal antibody and a recombinant antibody.

86. (Previously presented) A kit according to claim 84, wherein said competitor is labeled.

87. (Previously presented) A kit according to claim 84, wherein said competitor is immobilized to a solid phase.

88. (Currently Amended) A kit according to claim 84, wherein said contacting means enables contact of said competitor with said (i) TSH receptor or ~~(ii) TSH receptor fragment~~ after contact of said (i) TSH receptor or ~~(ii) TSH receptor fragment~~ with said antibody of (b).

89. (Currently Amended) A kit according to claim 84, wherein said contacting means enables contact of said competitor with said (i) TSH receptor or ~~(ii) TSH receptor fragment~~ before or concurrent with contact of said (i) TSH receptor or ~~(ii) TSH receptor fragment~~ with said antibody of (b).

90. (Previously presented) A kit according to claim 77, which further comprises a binding agent specific for said autoantibodies present in said sample of body fluid being screened and whereby said contacting means enables contact of said binding agent with said autoantibodies present in said sample of body fluid being screened.

91. (New) A kit for use in screening a sample of body fluid for autoantibodies to the TSH receptor, which kit comprises:

- (a) at least one antibody, or fragment thereof, that binds to an epitope present in, or derived from, the last 160 amino acids of the TSH receptor, with which autoantibodies to the TSH receptor do not interact;
- (b) a source of TSH receptor comprising (i) a first binding region comprising said epitope with which said antibody of (a) binds, and which is present in, or is derived from, the last 160 amino acids of the TSH receptor, and (ii) a second binding region comprising at least one epitope with which autoantibodies to the TSH receptor interact, said first and second binding regions being such that said TSH receptor retains its ability to bind TSH receptor autoantibodies in addition to binding with said antibody of (a), whereby said TSH receptor can concurrently bind:

said antibody of (a) at said epitope of said first binding region of said TSH receptor; and

TSH receptor autoantibodies, when present in said sample of body fluid being screened, at said epitope of said second binding region of said TSH receptor;

(c) means for contacting said TSH receptor of (b) with:

said sample of body fluid being screened; and
said antibody of (a);

whereby said contacting means allow said antibody of (a) to bind said epitope of said first binding region of said TSH receptor of (b), and said autoantibodies when present in said sample of body fluid being screened to concurrently bind with said epitope of said second binding region of said TSH receptor of (b); and

(d) means for monitoring binding of said autoantibodies and said TSH receptor of (b), so as to provide an indication of the presence of TSH receptor autoantibodies in said sample of body fluid being screened.

92. (New) A kit for use in screening a sample of body fluid for autoantibodies to the TSH receptor, which kit comprises:

(a) antibody Mab 4E31, or fragment thereof;

(b) a source of TSH receptor comprising (i) a first binding region comprising an epitope with which antibody Mab 4E31 of (a) binds, and which is present in, or is derived from, the last 160 amino acids of the TSH receptor, and (ii) a second binding region comprising at least one epitope with which autoantibodies to the TSH receptor interact, said first and second binding regions being such that said TSH receptor retains its ability to bind TSH receptor autoantibodies in addition to binding with antibody Mab 4E31 of (a), whereby said TSH receptor can concurrently bind:

antibody Mab 4E31 of (a) at said epitope of said first binding region of said TSH receptor; and

TSH receptor autoantibodies, when present in said sample of body fluid being screened, at said epitope of said second binding region of said TSH receptor;

(c) means for contacting said TSH receptor of (b) with:

said sample of body fluid being screened; and
antibody Mab 4E31 of (a);

whereby said contacting means allow antibody Mab 4E31 of (a) to bind said epitope of said first binding region of said TSH receptor of (b), and said autoantibodies when present in said sample of body fluid being screened to concurrently bind with said epitope of said second binding region of said TSH receptor of (b); and

- (d) means for monitoring binding of said autoantibodies and said TSH receptor of (b), so as to provide an indication of the presence of TSH receptor autoantibodies in said sample of body fluid being screened.